

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Shankara et al. CONFIRMATION NO:
SERIAL NO: Not Yet Known GROUP NO: Not Yet Known
FILING DATE: August 10, 2001 EXAMINER:
TITLE: ANTIGENIC PEPTIDE CONCATOMERS

Box Patent Applications
Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

This Preliminary Amendment is being filed prior to examination of the above-identified application. This Preliminary Amendment accompanies a request under 37 C.F.R. § 1.53(b) to file a nonprovisional patent application.

Please amend the application as follows:

In the Claims:

Please cancel claims 4-6, 8-10, 30 and 31, without prejudice.

Please amend claims 1-3, 7, 11-15, 17-19, 22-25, 29, 32, 34, 35 and 38 as follows:

1. (Amended) A recombinant polynucleotide comprising a plurality of first polynucleotides, each of said plurality of first polynucleotides encoding a first antigenic peptide and wherein the first polynucleotides are operatively linked to each other to enhance translation

of the polynucleotides to the antigenic peptide and binding of the antigenic peptide to MHC molecules.

2. (Amended) The recombinant polynucleotide of claim 1, further comprising a plurality of second polynucleotides, each of said plurality of second polynucleotides encoding a second antigenic peptide, said second peptide having an amino acid sequence that is different from the peptides encoded by the first polynucleotides.

3. (Amended) The recombinant polynucleotide of claim 1, wherein the plurality of first polynucleotides comprises at least 2, or 7, or 9, or 13 or more copies of the first polynucleotide.

7. (Amended) The recombinant polynucleotide of claim 2, wherein the plurality of second polynucleotides comprises at least 2, or 7, or 9, or 13 or more copies of the second polynucleotide.

11. (Amended) The recombinant polynucleotide of claim 1 or 2, further comprising a promoter operatively linked to the polynucleotide.

12. (Amended) The recombinant polynucleotide of claim 1 or 2, further comprising a polynucleotide encoding a cytokine.

13. (Amended) The recombinant polynucleotide of claim 1 or 2, further comprising a polynucleotide encoding a costimulatory molecule.

14. (Amended) The recombinant polynucleotide of claim 1 or 2, further comprising a polynucleotide encoding a cytokine and a polynucleotide encoding a costimulatory molecule.

15. (Amended) The recombinant polynucleotide of claim 1 or 2, further comprising a polynucleotide encoding a plurality of amino acids inserted between each of said plurality of polynucleotides encoding the antigenic peptides.

17. (Amended) The recombinant polynucleotide of claim 1 or 2, further comprising a polynucleotide having mRNA stability activity operatively linked to the polynucleotides encoding the antigenic peptides to stabilize the mRNA transcribed from the recombinant polynucleotide.

18. (Amended) The polynucleotide of claim 17, wherein the polynucleotide having mRNA stability activity is the 3' UTR of the α -globulin gene.

19. (Amended) The recombinant polynucleotide of claim 1 or 2, wherein the antigenic peptide is an antigenic fragment of a tumor associated antigen.

22. (Amended) The recombinant polynucleotide of claim 19, wherein the antigenic fragment of a tumor associated antigen is epitope 209 of gp100.

23. (Amended) The recombinant polynucleotide of claim 1 or 2, wherein the antigenic peptide is a fragment of pathogenic antigen.

24. (Amended) The recombinant polynucleotide of claim 23, wherein the pathogen is a bacteria or virus.

25. (Amended) A gene delivery vehicle comprising the recombinant polynucleotide of claim 1 or 2.

29. (Amended) A host cell comprising the recombinant polynucleotide of claim 1 or 2.

32. (Amended) The host cell of claim 29, wherein the cell is a mammalian cell.

34. (Amended) The host cell of claim 32, wherein the mammalian cell is an antigen presenting cell.

35. (Amended) A method for presenting antigenic epitopes on the surface of an antigen presenting cell comprising introducing the recombinant polynucleotide of claim 1 or 2 into said antigen presenting cell under suitable conditions such that the polynucleotide encoding the antigenic peptide is translated and presented on the surface of the antigen presenting cell.

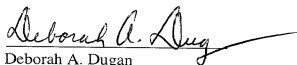
38. (Amended) A method of modulating an immune response in a subject, comprising administering to the subject an effective amount of the recombinant polynucleotide of claim 1 or 2.

REMARKS

Claims 1-43 are pending in the subject application. Claims 4-6, 8-10, 30 and 31 have been canceled without prejudice. Claims 1-3, 7, 11-15, 17-19, 22-25, 29, 32, 34, 35 and 38 have been amended. No new matter has been added. Support for the amendments is found throughout the specification and claims as originally filed.

No fee is believed necessary in connection with the filing of this Preliminary Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,



Deborah A. Dugan
Attorney for the Applicants
Reg. No. 37,315

Date: August 10, 2001

Genzyme Corporation
15 Pleasant Street Connector
Framingham, MA 01701-9322
Tel. No.: (508) 270-2598
Fax No.: (508) 872-5415

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 4-6, 8-10, 30 and 31 have been canceled, without prejudice.

Claims 1-3, 7, 11-15, 17-19, 22-25, 29, 32, 34, 35 and 38 have been amended as follows:

1. (Amended) A recombinant polynucleotide comprising a plurality of first polynucleotides, each of said plurality of first polynucleotides encoding ~~an identical~~ a first antigenic peptide and wherein the first polynucleotides are operatively linked to each other to enhance translation of the polynucleotides to the antigenic peptide and binding of the antigenic peptide to MHC molecules.

2. (Amended) The recombinant polynucleotide of claim 1, further ~~comprising~~ comprising a plurality of ~~a second polynucleotide~~ polynucleotides, each of said plurality of second polynucleotides encoding ~~multiple copies of a second~~ antigenic peptides peptide, said second peptide having an amino acid sequence that is different from the peptides encoded by the first polynucleotides.

3. (Amended) The recombinant polynucleotide of claim 1, wherein the plurality of first polynucleotides is 2 or more ~~comprises at least 2, or 7, or 9, or 13 or more copies of the first polynucleotide.~~

7. (Amended) The recombinant polynucleotide of claim 2, wherein the plurality of second polynucleotides ~~is 2 or more~~ comprises at least 2, or 7, or 9, or 13 or more copies of the second polynucleotide.

11. (Amended) The recombinant polynucleotide of ~~claims~~ claim 1-40 or 2, further comprising a promoter operatively linked to the polynucleotide.

12. (Amended) The recombinant polynucleotide of ~~claims-claim 1-40~~ or 2, further comprising a polynucleotide encoding a cytokine.

13. (Amended) The recombinant polynucleotide of ~~claims-claim 1-40~~ or 2, further comprising a polynucleotide encoding a costimulatory molecule.

14. (Amended) The recombinant polynucleotide of ~~claims-claim 1-40~~ or 2, further comprising a polynucleotide encoding a cytokine and a polynucleotide encoding a costimulatory molecule.

15. (Amended) The recombinant polynucleotide of ~~claims-claim 1-40~~ or 2, further comprising a polynucleotide encoding a plurality of amino acids inserted between ~~the each of said~~ plurality of polynucleotides encoding the antigenic peptides.

17. (Amended) The recombinant polynucleotide of ~~claims-claim 1-40~~ or 2, further comprising a polynucleotide having mRNA stability activity operatively linked to the polynucleotides encoding the antigenic peptides to stabilize the mRNA transcribed from the recombinant polynucleotide.

18. (Amended) The polynucleotide of claim-12 ~~17~~, wherein the polynucleotide having mRNA stability activity is the 3' UTR of the α -globulin gene.

19. (Amended) The recombinant polynucleotide of ~~claims-claim 1-40~~ or 2, wherein the antigenic peptide is an antigenic fragment of a tumor associated antigen.

22. (Amended) The recombinant polynucleotide of claim 19, wherein the antigenic fragment of a tumor associated antigen is ~~gp~~ epitope 209 of gp100.

23. (Amended) The recombinant polynucleotide of ~~claims-claim 1-10 or 2~~, wherein the antigenic peptide is a fragment of pathogenic antigen.

24. (Amended) The recombinant polynucleotide of ~~claims-claim 23~~, wherein the pathogen is a bacteria or virus.

25. (Amended) A gene delivery vehicle comprising the recombinant polynucleotide of ~~claims-claim 1-10 or 2~~.

29. (Amended) A host cell comprising the recombinant polynucleotide of ~~claims-claim 1-10 or 2~~.

32. (Amended) The host cell of claim 29-~~or 31~~, wherein the cell is a mammalian cell.

34. (Amended) The host cell of claim ~~31~~32, wherein the ~~dendritic~~ mammalian cell is an antigen presenting cell.

35. (Amended) A method for presenting antigenic epitopes on the surface of an antigen presenting cell comprising introducing the recombinant polynucleotide of ~~any of claims claim 1-10- or 2 into said antigen presenting cell~~ under suitable conditions such that the polynucleotide encoding the antigenic peptide is translated and presented on the surface of the antigen presenting cell.

38. (Amended) A method of modulating an immune response in a subject, comprising administering to the subject an effective amount of the recombinant polynucleotide of ~~claims-claim 1-10 or 2~~.